

Serial No.: 10/519,704
Filed: December 5, 2005
AMENDMENT AND
RESPONSE TO OFFICE ACTION

Remarks

Claims 12-23 and 28-36 are pending upon entry of the foregoing amendments.

Examiner Interview

Applicants thank Examiners Kelly Bekker and Lien Tran for the helpful interview with Elizabeth Lester, agent for the Applicants, on May 24, 2010, regarding the Office Action mailed February 19, 2010. In the interview, the agent for the Applicants discussed Applicants' claimed invention and technology, the rejections of the claims under 35 U.S.C. § 112, second paragraph, and the rejections of the claims over the prior art of record. In particular, agent for the Applicants discussed the combination of the cited references and Applicants' evidence of surprising and unexpected results.

Amendments to the Claims

Claims 1-11 were previously cancelled and claims 24-26 were previously withdrawn as being drawn to a nonelected species. Applicants respectfully submit that rejoinder of claims 24-26 may be appropriate once a common technical feature is determined to be patentable.

Claims 12 and 28 have been amended to include the language of claim 27. Claim 27 has been cancelled. No new material is believed to be added by these amendments.

Rejection Under 35 U.S.C. § 112

Claims 12-23 and 27-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for omitting essential steps. Specifically, the Examiner argues that the claims are indefinite because the step of further de-esterifying the pectin from a DE of 30-60% to a DE of

under 30%, as set forth in claims 15-17 and 31-33, is omitted. (Office Action at pages 2-3). The rejection is respectfully traversed.

The M.P.E.P. notes that “[d]efiniteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” (M.P.E.P. § 2173.02). Here, one of ordinary skill in the art would readily be able to appreciate the scope of the claims when read in light of both the Specification and the knowledge of those of ordinary skill in the art.

Applicants respectfully submit that the rejection is improper as applied to claims 12-14, 18-23, 27-30, and 34-36 because these claims do not limit the amidated de-esterified pectin to a DE of under 30%. Thus, the step of de-esterifying the pectin from a DE of 30-60% to a DE of under 30% is not an omitted essential element of claims 12-14, 18-23, 27-30, or 34-36.

Applicants further submit that the omitted step also is not an essential element of claims 15-17 or 31-33 because a certain amount of de-esterification of the pectin may be expected during the amidation of the de-esterified pectin, and thus is inherent in the process as claimed. (See e.g., Published Application at Example 2, Tables 2.1 and 2.2) (showing that de-esterified pectins having a DE greater than 30.0% produced amidated de-esterified pectins having a DE of under 30.0% after amidation without a separate step of de-esterification). Accordingly, withdrawal of the rejection is respectfully requested.

Serial No.: 10/519,704
Filed: December 5, 2005
AMENDMENT AND
RESPONSE TO OFFICE ACTION

Rejection Under 35 U.S.C. §103

Claims 12-23 and 27-36 are rejected under 35 U.S.C. § 103(a) as being obvious over International Publication WO 99/37685 to Marr et al. (hereinafter “Marr”) in view of International Publication WO 98/58968 to Larsen et al. (hereinafter “Larsen”). The rejection is respectfully traversed.

The Examiner continues to erroneously rely on the combination of Marr and Larsen to read on the Applicants’ claimed amidated de-esterified pectins by disregarding the portions of the references which teach away from the proposed combination. Applicants respectfully submit that the upon consideration of the entire record, including the affidavit of a scientist having over 35 years of experience in the field of the invention, the evidence is insufficient to establish a *prima facie* case of obviousness by a preponderance of the evidence (i.e., more probable than not).

The Prior Art References Teach Away from the Proposed Combination of References

“A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” (M.P.E.P. §2141.02). Here, portions of both cited references teach away from the desirability of various elements of Applicants’ claimed amidated de-esterified pectins. These teachings can not be merely dismissed.

Marr teaches that it is necessary to reduce the molecular weight of bulk-extracted pectin to improve the solubility of the de-esterified pectins. In particular, Marr discloses methods for preparing pectins having both a low degree of esterification and a reduced molecular weight in the range of 20,000 to 50,000 Daltons and describes the resulting de-esterified pectins as having good solubility, heat stability, and rheological properties.

Larsen teaches that it is essential to separate pectin fractions to eliminate the undesirable properties of bulk-extracted pectins. Larsen observes that:

The characteristics of [bulk] extracted pectin products can be defined only in a statistical manner because of the variability in polymerisation, methoxylation and acetylation, neutral sugar content, and distribution of substituents along the backbone. It is reasonable to assume that not two pectin molecules in a bulk-extracted pectin preparation are identical. ... *Thus, two pectin molecules having the same molecular mass and the same esterification may interact differently with another molecule, particle or ion.*"

(page 4, lines 8-21) (*emphasis added*). Larsen further teaches that the bulk extracted pectin produces products having a number of undesirable properties (e.g., haze in gels, enhanced viscosity, incomplete solubility, and syneresis) and that it is possible to overcome by extracting high-ester pectin fractions instead of merely bulk-extracted pectin. These pectin fractions optionally may be de-esterified and/or amidated to obtain de-esterified and amidated pectin fractions.

As Applicants have previously argued, the references, when considered in their entirety, teach away from the Examiner's proposed combination. While Marr is directed to bulk-extracted pectins, Larsen is directed to pectin fractions and expressly teaches that use of bulk-extracted pectins is undesirable. One skilled in the art would not rely on Larsen's disclosure of amidated pectins while simultaneously disregarding Larsen's disclosure that teaches away from use of bulk-extracted pectins.

The Examiner does precisely that, however, arguing that "the bulk pectin as taught by Marr includes pectin fractions and thus the process of Larson which enhances the pectin fractions would also enhance the pectin fractions in the bulk pectin, thus enhancing the bulk

pectin as taught by Marr.” (Office Action at page 6). This reasoning, however, disregards the teachings of the references in their entirety.

The prior art perceived a need to improve the performance of bulk-extracted pectins by either reducing both the degree of esterification and the molecular weight of the bulk-extracted pectins (as taught in Marr) or by using pectin fractions in lieu of bulk-extracted pectins (as taught in Larsen). Applicants, however, have eliminated the need for either of these solutions by instead reducing only the degree of esterification of the bulk-extracted pectins and subsequently amidating the de-esterified pectins.

The Combination of References Would Not Have Produced Predictable Result

A combination of known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art. (M.P.E.P. § 2143). Applicants respectfully submit that the Examiner has failed to establish that the teaching of Larsen and Marr would have produced a predictable result. That is, the Examiner has failed to demonstrate by a preponderance of the evidence that amidation of the modified pectins of Marr would provide the amidated de-esterified pectins set forth in the claims.

As noted above, Larsen clearly teaches that when the same product is treated in substantially the same manner it does not necessarily result in the same final product. Based on this teaching, one skilled in the art would have no reason to believe that amidating a bulk-extracted pectin would provide the same benefits observed upon amidating a pectin fraction. On the contrary, one skilled in the art clearly would read Larsen as teaching that the only way to achieve a predictable result with extracted pectins would be to recover a specific pectin fraction.

The Combination of References Does Not Teach the Claimed Invention

Moreover, even if one skilled in the art were to combine the references, the combination would fail to teach or suggest the amidated pectins having the claimed characteristics or methods for preparing the amidated pectins. For example, neither of the cited references remotely teaches or suggests the desirability of minimizing the loss of the molecular weight during the de-esterification of the pectin such that the de-esterified pectin is characterized by having a ratio, R, of molecular weight of the starting pectin material to the molecular weight of the de-esterified pectin up to 1.15 as set forth in independent claims 12 and 28. Nor do the cited references remotely teach or suggest the desirability of minimizing the loss of intrinsic viscosity during the amidation of the pectin such that the amidated de-esterified pectin is characterized by having a ratio, R2, of intrinsic viscosity of the de-esterified pectin to the intrinsic viscosity of the amidated pectin within the ranges set forth in dependent claims 13-14 and 29-30.

The Examiner seemingly dismisses each of these limitations by suggesting that the “features upon which applicant relies … are not recited in the rejected claims(s).” (Office Action at page 7). Specifically, the Examiner argues that “there is nothing claimed recited that the final product has a high molecular weight, nor is there any limitation preventing the decrease of the molecular weight of the high molecular weight pectin of the sub-step” and “that as the references of record teach that the product is treated in substantially the same manner, i.e. amidation by ammonia to produce an amidated pectin, one of ordinary skill in the art would expect substantially the same results in the final product … that is substantially the same as the instantly claimed invention.” (Id.).

Although Applicants claims do not expressly provide for preventing a significant decrease of the molecular weight of the de-esterified pectin during the amidation step, one skilled in the art would appreciate that the subsequent amidation of the de-esterified pectin “will have little impact on the molecular weight of the pectin because the number of ester groups have [already] been substantially reduced in the first part of the process.” (Published Application at paragraph [0043]). Moreover, Applicants claims do expressly provide for preventing significant decreases in the intrinsic viscosity of the de-esterified pectin during the amidation step. One skilled in the art would appreciate that the intrinsic viscosity and Mark Houwink factor are correlated to molecular weight. Applicants claims thus similarly would inherently provide for preventing the significant decrease of the molecular weight of the high molecular weight pectin during the amidation step. Neither Marr nor Larsen remotely teach or suggest the desirability of preventing the significant decrease of the molecular weight during the de-esterification and amidation of the pectin. As noted above, Marr actually teaches the opposite – that the molecular weight of the pectin is desirable.

Applicants respectfully submit that if one skilled in the art were to combine Marr and Larsen, a more plausible combination of the references would provide a method for preparing the high-ester pectin fractions using the teachings of Larsen, both reducing the degree of esterification and molecular weight using the teachings of Marr, and amidating the low molecular weight de-esterified pectins to provide amidated de-esterified pectin fractions having a low degree of esterification and a low molecular weight. The resulting product would not be an amidated pectin having a low degree of esterification and a high molecular weight having the limitations set forth in the claims.

Secondary Considerations Overcome the Alleged *Prima Facie* Case of Obviousness

Even if the Examiner had set forth a *prima facie* case of obviousness, Applicants' surprising and unexpected results are sufficient evidence of secondary considerations to establish the nonobviousness of Applicants' claimed invention. Applicants have discovered that by first de-esterifying the pectin using biocatalytic de-esterification and subsequently amidating the de-esterified pectin, the depolymerization and aggregation of the amidated pectins can be significantly reduced.

The Examiner attempts to rebut the evidence of secondary considerations previously set forth by Applicants, arguing that the comparative tests only show a pectin treated by acid de-esterification and not enzymatic or biocatalyst de-esterification. As Applicants previously have demonstrated, however, amidating the de-esterified pectins of Marr will not provide the Applicants' claimed invention absent an understanding of the importance of avoiding the reduction of molecular weight of the pectin during both the de-esterification and amidation steps and the concomitant effect of any reduction in molecular weight on the intrinsic viscosity and Mark-Houwink factor. Applicants have discovered that exemplary amidated pectins have a surprisingly high molecular weight, a surprisingly low loss of intrinsic viscosity, and produce gels having surprisingly good rheological properties.

In light of the foregoing facts and legal standards, Applicant respectfully submits that the combination of references fails to render obvious Applicant's claimed compositions and methods. The rejections therefore must be withdrawn.

Serial No.: 10/519,704
Filed: December 5, 2005
AMENDMENT AND
RESPONSE TO OFFICE ACTION

Conclusion

For the foregoing reasons, Applicants respectfully submit that all claims are patentable. Allowance of all claims is respectfully requested. If there are any issues which can be resolved by telephone conference or an Examiner's Amendment, the Examiner is invited to contact the undersigned attorney at 404.853.8012 or elizabeth.lester@sutherland.com.

Respectfully submitted,



By: Elizabeth A. Lester
Reg. No. 55,373

Date: June 21, 2010

SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street, N.E.
Atlanta, Georgia 30309-3996
Telephone: (404) 853-8012
Facsimile: (404) 853-8806

Docket No.: 04-501 (29776-0005)